Basic Building Block Profile

Building Block: Setup and Design

Vision

A compliant suite of access-controlled clinical and operational systems and document storage system which support site selection and initiation, GCP-compliant trial conduct, timely data entry and data integrity, and regulatory-filing documentation. This suite drives inspection-readiness by funneling all required clinical oversight and study operational oversight to performance monitoring and operational analytics dashboards.

Systems must be configured to accommodate multiple, simultaneous end-users access and meet GDPR adherence requirements (e.g. 2-factor authentication), and data/records protection and retention. System training, business continuity planning, user acceptance testing, automated functionality (e.g. auto-save; auto-log-off for idle periods), and tech support ("help desk") will be prerequisites.

Included activities in the RFP

The following activities are included in the RFP:

1. Operational feasibility and site selection
2. Study branding
3. IMP supply

OPERATIONAL FEASIBILITY AND SITE SELECTION

IMI/Trials@Home WP EAGLE has completed EU member country feasibility assessments. The contracted vendor would be required to demonstrate an access-controlled, fully-functional, electronic site feasibility and site selection system (including but not limited to site outreach survey; investigator trial experience; enrollment estimates; contracting timelines estimation), as well as site initiation visit processes tracking. These access-controlled systems must be accessible to the study operational oversight team.

The contracted vendor would be required to (1) conduct investigational site selection within IMI/Trials@Home selected countries for the classical clinical trial (CCT) arm and hybrid arm (Part A) portion of the study conduct and (2) pivot to recruitment of a purely decentralized arm, when necessary. The contracted vendor would be expected to provide solutions for recruitment of the purely decentralized arm that address current EU and local laws and regulations. For all selected investigational sites, the contracted vendor should be able to demonstrate a compliant Investigational Site Master File system, rater qualification training and tracking system.

IMP SUPPLY

Decentralized trials arms face unique challenges regarding Direct-to-Participant (DtP) IMP shipments based upon current EU and local laws and regulations. A contracted vendor must be able to demonstrate expertise executing the multi-step processes from (1) IRT/Drug Order to (2) Drug Delivery to Participants to (3) Drug Supply and Re-supply to (4) IMP returns to Central supplier assessment of drug compliance/exposure to (5) IMP destruction.

The research leading to these results has received support from the EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking (H2020-JTI-IMI2) Trials@Home grant n° 831458.

STUDY BRANDING
While listed as a functionality under Setup and Design BBB, study branding activities have been relegated to Patient Engagement BBB and Recruitment and Enrollment BBB.

Excluded activities from the RFP

The activities below are already covered by internal partners and **excluded from the RFP**:

- Create participant and site education strategy
- Site Start-up
- Operational setup
- Obtain Ethics & Regulatory approvals
- Technology setup
- Protocol development
- Trial Registration
- Online platform for study specific information (landing page and pre-screener) in desktop and mobile functionality

RFP – Knockout Criteria

For the activities included in the RFP we have identified a number of knockout criteria that will exclude the technology vendor in the case that one or more of them are not met.

<u>Operational feasibility and site selection</u>

The technology will be rejected if:

1) Not able to demonstrate prior cases of at least two different clinical trials wherein Operational Feasibility and Site Selection systems were successful.
2) Not able to demonstrate prior cases of at least two different clinical trials wherein Operational Feasibility and Site Selection systems were successful and met GCP standards
3) Demonstration of above systems do not conform to reviewers' expectations.

<u>IMP supply</u>

The technology will be rejected if:

1) Not able to demonstrate prior cases of at least two different clinical trials wherein IMP (from study drug assignment to drug destruction) and met EMA inspection standards.
2) Demonstration of IMP management systems do not conform to reviewers' expectations.

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